



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Release Notes

PSUR Repository

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About this Document

This document lists and briefly describes the new features and fixed issues included in each release of the PSUR Repository.

The most recent release appears first.

The known issues are categorised per component or business process of the system so that users can easily identify which issues are relevant for them. The components currently used are:

Component	Short Description
NCA UI	The user interface (UI) used by NCA users to search and retrieve PSUR related documents and to upload assessment reports and related
Delivery File UI	The user interface (UI) used by MAHs to generate the delivery file with the metadata needed to submit and process the PSUR documentation.
eSubmission Process	The business process whereby MAHs submit electronically PSUR documentation to the PSUR Repository and the system then automatically processes this and makes it available in the Repository
DREAM	The EMA's document management system, used to host the PSUR Repository.
Notifications	The functionality that sends notifications to NCAs upon certain pre-defined events happening.
EMA Admin UI	The user interface (UI) used by EMA to support the PSUR processing process.
eSub GW	eSubmission Gateway
API	The Application Programming Interface allowing NCA IT systems to automatically exchange information with the PSUR Repository.

For the purpose of this document, a change request (CR) is defined as an additional functionality that was not included in the original requirements of the software.

For additional information on the PSUR Repository see:

- The [PSUR Repository webpage](#) gives access to all documentation.
- Regular training sessions are being organised. See the [PSUR Repository webpage](#) for more information.
- User guidance documentation on the [PSUR Repository webpage](#) provides answers to most common problems.
- If you encounter any issue that is not addressed by the above, contact the EudraService@ema.europa.eu.

Version 01.11.00 (Release Date: 31st March 17)

What's New

This release provides the following change requests.

Version 01.11.00 of the PSUR Repository is released combined with version 3.2.0-RC2 of the eSubWeb and v 3.7.2-RC3 Gateway file handler.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect Fix
SD-81652	API	When a search is launched for AR template and the document is not present in the repository an error code 500 was presented instead of 'document not found' response.
SD-72409	Delivery file creation	PSUSA Repository XML delivery file creation – responses cannot be submitted before the 'initial' PSUR has been submitted to the repository. Business rule has been modified to prevent 'responses' being submitted prior to the 'PSUR'. If submission deadline has been passed, the MAH must contact EMA to request for late submission ID instead of submitting the PSUR using incorrect submission unit (response).
SD-85240	Admin UI	EMA super admin now has the ability to delete supplemental information submissions from the Non-EU Single Assessment area of the PSUR repository

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 0 open defect listed.

ID	Component	Description	Workaround/Comment
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Version 01.10.00 (Release Date: 20 Feb 17)

What's New

This release provides the following change requests.

Version 01.10.00 of the PSUR Repository is released combined with version 3.1.0-RC1 of the eSubWeb and v 3.7.1-RC1 Gateway file handler.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect Fix
SD-72659	Delivery file UI	Allow selection of herbal and homeopathic products for submission when preparing XML delivery file for PSUSA/non-EU PSUR submissions
SD-45843	Delivery file UI	Functionality to indicate whether the submission contains an updated RMP and to provide the relevant RMP number (for CAPs only).
	Notifications	Information on the inclusion of the RMP and the RMP number if relevant is now included in the Excel report included in the submission deadline notification.
SD-66242	Notifications	All relevant PSUR repository notifications now contain a link to EMA document management system (PSUR Repository EMA user interface via DREAM) to facilitate work of EMA colleagues. This link only works for EMA users
SD-45850	Notifications	Product ATC code is now included in the Excel report included in the submission deadline notification
SD-53626	NCA notifications	PSUR Repository AR reminder notifications are not send for procedures for which no PSURs have been submitted

ID	Component	Brief Description of the CR or Defect Fix
SD-49077	EMA notifications	Defect relating to occasional missed PSUR repository notifications to EMA Procedure Manager/Procedure Assistant has been fixed and all relevant notifications are now sent to the allocated PM/PA
SD-69535	EMA notifications	Notifications to Outlook mailbox to alert EMA procedure assistant if product 'bucket' changes occur between DLP and start date
PSUR-668	eSubmission Gateway Acknowledgement	Failure acknowledgement sent to MAH/sender when same 'Late Submission ID' used for more than one PSUR submission
SD-50540	EMA admin UI	Ability for EMA super admin user to delete comments in the PSUR Repository upon request from NCAs.
SD-56740	EMA admin UI	Ability for EMA super admin user to delete Non-EU PSUSA PSUR submissions
SD-71595	EMA admin UI	Deletion/Invalidation of EU PSURs/Responses by super admin/NCA in PSUR repository are reflected in EMA document management system (DREAM)
SD-45849	API	Assessment Report templates are now available via the API

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 0 open defect listed.

ID	Component	Description	Workaround/Comment
SD-79991	NCA notifications	PSUR Repository AR reminder notifications are sent for PSUSA procedures which are deemed non-starters but for which a PSUR has been submitted.	This issue will be fixed in the next release planned for March/April 2017.

Version 01.08.01 (Release Date: 6 Oct 16)

What's New

This release provides the following change request.

Version 01.08.00 of the PSUR Repository is released combined with version 2.0.0-RC8 of the eSubWeb and v3.6.0-RC6 Gateway file handler.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect Fix
SD-50120	API	Missing sup info – org version change
SD-49166	Gateway filehandler zip file validation	Restricting sending of 2 separate sequences within one submission zip package
SD-45755	Data fix	Delete PAR for specific procedure only
SD-50682	API	Marketing authorization mapping missing for 12
SD-45972/SD-47765	API	Call to retrieve submissions with query modifiedTo – modifiedFrom will now reflect all document types available in the repository
SD-51444/SD-51494	Delivery File UI	Remove filters on product search during supplemental info (response) delivery file creation
SD45327	Data fix	Delete comment for specific procedure only

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 0 open defect listed.

ID	Component	Description	Workaround/Comment

Version 01.08.00 (Release Date: 20 Sep 16)

What's New

This release provides the following change request.

Version 01.08.00 of the PSUR Repository is released combined with version 03.06.00 of the eSubmission Gateway File Handler.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect Fix
SD-29491	Psur Repository	Missing products in PSUR Repository
SD-44656	Psur Repository	Issue with PSUR repository - product renewal blocked by missing PSUR submission

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 0 open defect listed.

ID	Component	Description	Workaround/Comment

Version 01.07.00 (Release Date: 25 July 16)

What's New

This release provides the following change request.

Version 01.07.00 of the PSUR Repository is released combined with version 03.06.00 of the eSubmission Gateway File Handler.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect Fix
SD-7706		Compliance to the new Specification of "EU Module1 eCTD v.3.0 Please see document below for details of changes: SD 7706-Psur repo changes EMA/337926/2016 https://docs.eudra.org/webtop/drl/objectId/090142b28340e25a
PSUR-601	API	No Sub unit information in API response
PSUR-602	Delivery File UI	GW error while uploading supplemental info via GW
PSUR-603	Delivery File UI	LATESUBMISSION id box is shown as empty?
PSUR-604	Notifications	Same Supplemental Info Notification is received twice?
PSUR-605	NCA UI	Invalidate & Revoke notification received for supplemental info does not specify Submission unit
PSUR-606	Delivery File	Error -- Submission Deadline has passed for the procedure number while generating delivery file for Noneu submission -

ID	Component	Brief Description of the CR or Defect Fix
	UI	Late submission functionality available
PSUR-607	Delivery File UI	Products does not exists in ART57 error while adding products in prepare screen
PSUR-608	Delivery File UI	Products not available for MAH
PSUR-609	Notifications	PA/PM from siamed should be retrieved from product level instead of application
PSUR-610	Notifications	
PSUR-611	Delivery File UI	Error Submission Deadline has passed for procedure when initial is selected
PSUR-615	NCA UI	Date range searches are not working in test or xcomp environments
PSUR-616	Delivery File UI	UAT - PSUR / PSUSA submission type as per EU M1
PSUR-617	Notifications	Change text in the body of AR Template Notification
PSUR-618	Notifications	Modification in notification text for Assessment Report template

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 0 open defect listed.

ID	Component	Description	Workaround/Comment

Version 01.06.00 (Release Date: 14 May 16)

What's New

This release provides change requests as prioritised by the PSUR Repository Project Advisory Group in January 2016.

Version 01.06.00 of the PSUR Repository is released combined with version **03.05.00** of the eSubmission Gateway File Handler.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect Fix
PSUR-506	EMA Admin UI	Improve the EMA admin screen to make xml delivery file preparation easier or change the UI to allow the MAH to create the xml delivery file for submissions after the deadline (manual trigger required by EMA via admin screen)
PSUR-160 emea00036518	EMA Admin UI, NCA UI	Ability to remove wrongly submitted documents
PSUR-498	Delivery File UI	Provide the functionality to create a unique name for each of the XML delivery file
PSUR-490	NCA UI	Functionality for not allowing the inconsistent replies into PSUR Repository
PSUR-158 emea00036513		Gateway - Improve error handling and messages
PSUR-240 emea00037167	DREAM	Create the PSUSA folders in Documentum part of the PSUR repository based on a supplied list of PSUSA numbers
PSUR-292 emea00038126	Delivery File UI, EMA Admin UI, NCA UI	Make user aware of errors that are not visible on the screen due to size of form
PSUR-348 emea00038705	DREAM	Repository - improvement proposal relating to the DREAM folder structure
PSUR-364 emea00038946	Delivery File UI	Prepare of delivery file to take the EMA product number from Art 57 instead of free text field.
PSUR-483	Delivery File UI, EMA Admin UI	Prepare screen: remove the section about routing ID when the GWFH 3 will be in place.
PSUR-151	Notifications	Have a special message in a notification for a procedure deadline without any PSUR

ID	Component	Brief Description of the CR or Defect Fix
emea00036464		
PSUR-350 emea00038709	NCA UI	Timestamp to be added to Date Received Column in results for Eu and Non-EU search
PSUR-365 emea00038948	NCA UI, EMA Admin UI	PSUR Repository: unable to search by procedure number if there is no PSUR in the procedure
PSUR-516	Notifications	Add PRAC (all human Pharmacovigilance) to distribution list for assessment report & comments notification
PSUR-491	Delivery File UI, EMA Admin UI, NCA UI	EMA strategy requires all applications to be IE11 compatible from early 16
PSUR-521	EMA Admin UI, NCA UI	"Search Result: Sort List of procedures by active substance (Alphabetically)"
PSUR-522	Notifications	"All notifications should refer to countries as: *CountryCode*"
PSUR-534	Notifications	"Functionality to include the details of the PA and the PM into the notifications"
PSUR-514	Notifications	Change in the body of the notification sent 2 days after the PAR submission (elaboration of EMEA-36902)
PSUR-553	Notifications	Remove message from body of PSUR notification (elaboration of PSUR-151)
PSUR-554	NCA UI	Make selection of "Is a regulatory action suggested?" mandatory (elaboration of PSUR-490)
PSUR-248	DREAM	Rename some folders in the DREAM PSUR submissions cabinet
PSUR-313	Notifications	Notification sent to all Member states upon Supplementary info being uploaded
PSUR-345	NCA UI	PSUR System does not allow upload of AR for submission for which only supplementary info exists
PSUR-347	Delivery File UI	Prepare Delivery File Screen > sequence number should be positioned higher
PSUR-487	DREAM	XCOMP set-up (request for new roles)
PSUR-509	API	Setup certificates on new weblogic environment (WebLogic Server Version: 12.1.2.0.0)
PSUR-362	EMA Admin UI, NCA UI	Date from and date to calendar popup misaligned in FF
PSUR-378	Delivery File UI	EMA Routing and Application Routing fields can overlap
PSUR-508	Notifications	PSUR notification
PSUR-486	EMA Admin UI, NCA UI	The response time Search Product Name is high
PSUR-437	Delivery File UI	Product selection in the prepare screen requires filtering
PSUR-297	EMA Admin	Different behaviour of search fields when trying search criteria and hitting return

ID	Component	Brief Description of the CR or Defect Fix
	UI, NCA UI	
PSUR-504	EMA Admin UI, NCA UI	Xcomp -- Getting Unauthorized error and also session getting session expired error
PSUR-361	EMA Admin UI, NCA UI	Select a 'Date From' value also updates the 'Date From' field with same value
PSUR-464	API	NON EU LIST PSUR Response Statement in the API SPEC states offset & count as part of response. Possibly a documentation error.
PSUR-341	EMA Admin UI, NCA UI	Product (MAH) field is only tool tipped for 5 seconds and it not possible to copy values from this column
PSUR-513	Notifications	Wrong wording for the notification for AR reminder.
PSUR-515	Delivery File UI	Submission deadline is not displayed on the psur prepare screen
PSUR-439	EMA Admin UI, NCA UI	Status 500 error found during performance test
PSUR-524	EMA Admin UI, NCA UI	Documentum DQL queries use wrong date format.
PSUR-519	EMA Admin UI, NCA UI	Error in logs while searching other documents when date received is used as criteria
PSUR-527	EMA Admin UI, NCA UI	Not able to search other documents when date received is selected
PSUR-530	Delivery File UI	Bootstrap lib version upgrade broken non-eu prepare screen layout
PSUR-531	EMA Admin UI, NCA UI	Make substance search case insensitive
PSUR-563	Notifications	Invalidation Notification mention the resubmission to be done in 10 Days which need to be amended to 14 days as per the requirement
PSUR-562	EMA Admin UI, NCA UI	PSUR Super Admin unable to search procedures with role
PSUR-567	NCA UI	Unable to create Comments
PSUR-560	EMA Admin UI, NCA UI	Invalidate, Revoke and Delete Popup window Format and readability
PSUR-564	Notifications	No Notification received when a PSUR invalidation is revoked from Super User
PSUR-566	Notifications	Duplicate Notifications received when a user invalidates PSUR & Supplemental info
PSUR-558	EMA Admin UI, NCA UI	Unable to copy the full content of the Products selected as part of PSUR Submission in PSUR Search Window
PSUR-565	Notifications	Incorrect Error Message from Gateway File handler

ID	Component	Brief Description of the CR or Defect Fix
PSUR-555	EMA Admin UI, NCA UI	The boot strap does not stop see the image
PSUR-544	EMA Admin UI, NCA UI	Late Submission ID after used for submission expected to be updated as used in the Latesubmission Grid Used column
PSUR-543	API	API Regression test failing post changes to the test environment
PSUR-542	EMA Admin UI, NCA UI	On updating a new PAR form by a different user the system does reflect the Latest Submitter, Country And date received
PSUR-556	EMA Admin UI, NCA UI	Application logs out while trying to invalidate PSUR
PSUR-536	Notifications	Send Notification not generated for some procedures
PSUR-533	NCA UI	Session Expired Error when moving from upload page to search page.
PSUR-535	EMA Admin UI, NCA UI	Date received search component not working properly
PSUR-529	EMA Admin UI, NCA UI	Error in date pickers after bootstrap version upgrade
PSUR-449	API	Medicinal Products are always shown as null in Get Procedure resource response for all valid 32 countries
PSUR-577	EMA Admin UI, NCA UI	PSUR Issues with IE 9
PSUR-578	EMA Admin UI, NCA UI	PSUR Search retrieves data which is not expected
PSUR-589	EMA Admin UI, NCA UI	Search does not bring data as expected and has performance issues
PSUR-559	EMA Admin UI, NCA UI	Invalidate Pop-up does not wrap the file name in to the box if the filename is too
PSUR-225	EMA Admin UI, NCA UI	Pen Test Findings Low Level
PSUR-574	Delivery File UI	Late Submission ID window is not wrapped properly when the window is not maximized.. see the images attached
PSUR-570	EMA Admin UI, NCA UI	User 401 Session expired log off screen error while using the different users in the same window
PSUR-575	Repository	Procedure Number is box is locked and unable to type when window is not maximum.. Works fine when window size is maximum
PSUR-572	API	Look Up of PRAC, CHMP & CMDH fails to retrieve data
PSUR-571	Delivery File UI	Remove the Submission Deadline has passed error from the PSUR prep screen
PSUR-568	EMA Admin	Users able to Download old Assessment report

ID	Component	Brief Description of the CR or Defect Fix
	UI, NCA UI	

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 1 open defect listed, none are of level critical or severe.

ID	Component	Description	Workaround/Comment
PSUR-582	API	API: modifiedFrom - modifiedTo is not searching across modifications of all types of document	

Version 01.05.00 (Release Date: 06 Jan 16)

What's New

This release provides the post-audit functionality as requested by the EMA MB in Dec 13. As per the plan agreed with the EMA MB in Jun 15 and the PSUR Repository Advisory Group, PMG1, PRAC, ... this functionality is provided by two deliverables:

- The Application Programming Interface (API):
 - In compliance with "PSUR Repository API Specification" as agreed with IT Directors and EUTEAB
 - Published on the [eSub website](#)
- The additional notifications:
 - In compliance with "Additional Notifications Specification" as agreed with IT Directors and EUTEAB
 - Published on the [eSub website](#) and also documented as CR 36902

In addition, this release also provides a series of change requests related to notifications as prioritised by the PSUR Repository Advisory Group.

Version 01.05.00 of the PSUR Repository is released combined with version 03.03.05-RC3 of the eSubmission Gateway File Handler.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

Note that EMA has transferred its defect/CR registration system from ClearQuest to Jira. As a result the numbering system and numbers of defects and CRs has changed: "emea000xxxxx" or "xxxxx" -> "PSUR-xxx". Both numbers are used in the list below in the items that existed already in ClearQuest.

ID	Component	Brief Description of the CR or Defect Fix
n.a.	API	The Application Programming Interface allowing NCA IT systems to automatically exchange information with the PSUR Repository. This fulfils post-audit functionality 2 (See doc EMA/681848/2013), in compliance with "PSUR Repository API Specification" (Doc EMA/224103/2015) as agreed with IT Directors and EUTEAB.
n.a.	Notifications	The additional notifications system This fulfils post-audit functionalities 3 and 4 (See doc EMA/681848/2013), in compliance with "Additional Notifications Specification" (Doc EMA/) as agreed with IT Directors and EUTEAB Also documented as CR 36902

ID	Component	Brief Description of the CR or Defect Fix
38209 PSUR-306	Notifications	Notification of submitted products
35853 PSUR-70	Notifications	Reconciliation of PSURs - related to BRQ-0005
36902 PSUR-205	Notifications	BRQ-0011: Procedure timetable (notifications)
38278 PSUR-312	Notifications	Notification to NCA User for a late submission
36758 PSUR-183	Notifications	BRQ-0012 Consolidated list of comments
38212 PSUR-308	Notifications	To attain a report to view the MSs, who have commented on a PSUSA Assessment Report
36752 PSUR-179	Notifications	BRQ-0016 - Notifications should include hyperlinks to documents
36464 PSUR-151	Notifications	Have a special message in a notification for a procedure deadline without any PSUR
36422 PSUR-141	Notifications	PSUR Repository Notifications
38280 PSUR-313	Notifications	Notification sent to all Member states upon Supplementary Info being uploaded
38274 PSUR-310	Notifications	Additional information required in the subject field for the Email
38211 PSUR-307	Notifications	Generate Line Listing of submitted products manually
35850 PSUR-67	Notifications	Prepopulated AR templates in repository
38080 PSUR-282	Delivery File UI	Fixed defect: Unexpected deselection of rows in the product table of the prepare screen
38080 PSUR-282	Delivery File UI	Unexpected deselection of rows in the product table of the prepare screen
38707 PSUR-349	NCA UI	Upload a comment does not always upload into Dream
39194 PSUR-400	Delivery File UI	Fixed defect: Field Labels with more than 1 word values on the Prepare submission are not correctly capitalised
39194 PSUR-400	Delivery File UI	Field Labels with more than 1 word values on the Prepare submission are not correctly capitalised
39200 PSUR-404	Delivery File UI	Fixed defect: Product Selection - CAP Product selected and saved produced validation which clears the EMA number of its default value
39200 PSUR-404	Delivery File UI	Fixed: Product Selection - CAP Product selected and saved produced validation which clears the EMA number of its default value
39327 PSUR-432	Notifications	Fixed defect: Products.xlsx column of 'MRP/DCP or CP Authorisation number' is confusing

ID	Component	Brief Description of the CR or Defect Fix
	NCA UI	
39327 PSUR-432	Notifications NCA UI	Fixed: Products.xlsx column of 'MRP/DCP or CP Authorisation number' is confusing
39335 PSUR-434	Delivery File UI	Fixed defect: duplicates in mv_psur_substance materialized view
39335 PSUR-434	Delivery File UI	Fixed: duplicates in mv_psur_substance materialized view
39375 PSUR-438	NCA UI	Fixed: Documents added through WebTop and added to Core Master File not always found
PSUR-440	DREAM NCA UI	Fixed: Search of document types does not bring back correct results (only when PRAC Recommendation, CHMP position, CMDh opinion are involved)
PSUR-442	API	Fixed: LookupComment Resource does not verify procedure number and respective comments
PSUR-444	API	Fixed: Lookup Assessment Report with Version parameter as optional throws 500 Error
PSUR-446	API	Fixed: Lookup Supplemental Info - Retrieve data only based on Supplemental info id and ignores ProcedureID
PSUR-447	API	Fixed: 200 status is received when Mandatory procedure number is not passed
PSUR-448	API	Fixed: Incorrect error message while PRAC Recommendation lookup using invalid PRAC id
PSUR-450	API	Fixed: Get Procedure - Country parameter is case sensitive
PSUR-451	API	Fixed: Get Procedure Country Parameter - Missing Validation
PSUR-452	API	Fixed: Get Procedure - Data Lock Point & submissiondeadline- Missing Validation
PSUR-453	API	Fixed: Get Procedure Lookup for an invalid procedure number returned http status 200 and a blank response
PSUR-454	API	Fixed: Look UP Related Document -- Only Retrieves data based on Document ID and completely ignores Country Code and Datalockpoint in the request
PSUR-455	API	Resolved Indirectly: Create Related Document - with Invalid Datalockpoint format throws (Assessment report cannot be submitted without submitting PSUR)
PSUR-457	API	Fixed: NON EU Supplemental info - Returns not found when in correct datalockpoint format
PSUR-458	API	Fixed: Lookup PSUR -- Retrieves data based on only ID
PSUR-459	API	Fixed: NON EU LOOK Supplemental info & Look UP PSURID -- retrieves data though the date formats are incorrect
PSUR-460	API	Fixed: Country Field is case sensitive in List PUSR resource
PSUR-461	API	Fixed: List PSUR resource throws not found error when datalock point is sent in invalid format
PSUR-463	API	Fixed: Look up CMDh Position & CHMP Positions- retrieves data only based one id and ignores Procedure number
PSUR-465	Notifications	Fixed: Products missing from PSUR notifications
PSUR-466	repository	Fixed: Create Assessment Report template throws an blank error

ID	Component	Brief Description of the CR or Defect Fix
PSUR-467	API	Fixed: Lookup Procedure was not supposed to return array, however the response is framed as array.
PSUR-468	API	Fixed: Look UP PSUR resource is behaving strangely. The items in the lookup are being sorted or being listed randomly
PSUR-469	Notifications	Fixed: Link in New Assessment Notification email does not take to screen with procedure_number and assessment report selected.
PSUR-470	API	Fixed: NON EU LIST PSUR is unable to retrieve data though we have data in the system
PSUR-471	API	Fixed: country field is case sensitive in DatalockPoint
PSUR-472	API	Fixed: Error for some of the response are returned as Array which should not be an array
PSUR-474	Notifications	Fixed: Discrepancies in the email received for AR template when compared with requirement template
PSUR-475	Notifications	Fixed: Overnight PSUR notifications are generated for Procedure where submission deadline expired in the last 24 hrs.
PSUR-476	API	Fixed: Get Assessment Report resource retrieves Assessment report Template details when version is left blank
PSUR-477	NCA UI	Fixed: PRAC Recommendation not found
PSUR-478	NCA UI	Fixed: Procedure Number is displayed as procedure Number in Search Screen in PSUR Repo --
PSUR-479	Notifications	Fixed: Notifications for 7 days is sending notifications every time the batch job runs and sending 2 notifications for the same procedure number
PSUR-480	Notifications	Fixed: No AR Notifications generated for procedure where par due date is 2 days older
PSUR-481	NCA UI	As Designed: Text Change -- Send notification should be change to Send Notification in PSUR Repo Search screen to make it in sync with other buttons in the window
PSUR-482	Notifications	Fixed: Same products in both submitted and not submitted sheets.
PSUR-484	Notifications	Fixed: Notifications, if in HTML, should have the same style
PSUR-485	NCA UI	Fixed: Upload button under search result does not work as expected
PSUR-488	NCA UI	Fixed: Downloading documents doesn't work in IE 9.0 after a certain limit
PSUR-489	API	Fixed: download throws Null pointer when called with procedure number with no assessment report submitted
PSUR-492	API	Rejected: 500 Internal Server Error for Comments data not found
PSUR-493	API	Fixed: Typo in PSUR response (submissionDeadlLine)
PSUR-494	API NCA UI	Fixed: Date parser is incorrect for query parameters
PSUR-495	API	Fixed: Look PSUR unable to retrieve data in application/octet-stream format
PSUR-496	API	Fixed: Error code is not correct when document not found
PSUR-501	API	Fixed: Location Header Missing from Response of Post Request (Create Assessment Report, Create Comments & Create related Document)
PSUR-502	API	Fixed: Only latest version of Assessment report is downloadable from API

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 16 open defects listed, one of severity level major.

ID	Component	Description	Workaround/Comment
PSUR-503	Notifications	PRAC,CHMP & CMDH Notifications are not in standard format.	
PSUR-464	API	NON EU LIST PSUR Response Statement in the API SPEC states offset & count as part of response. Possibly a documentation error.	NON EU LIST PSUR Response Statement in the API SPEC states offset & count as part of response. However the count is not part of PSUR list response. This may be a documentation error. Document Section -- List PSUR Resource under NON EU. Response Returns an array of PSUR resource representations together with count and offset.

ID	Component	Description	Workaround/Comment
<u>PSUR-462</u>	API	Unparsable Date error is received when no value for datalockpoint is provided	<p>Unparsable Date error is received when no value for datalockpoint is provided for the below resporces.</p> <p>List NONEU Supplemental info LIST NON EU PSUR</p> <p>Example request & response</p> <p>GET https://psur-repo-test.eudra.org/psur-rs/public//procedures/noneusa/FR//supplementalinfos HTTP/1.1 Accept-Encoding: gzip,deflate Authorization: Basic d2FsbGFjZW06UGFzc3dvcmQx Accept: application/json Host: psur-repo-test.eudra.org Connection: Keep-Alive User-Agent: Apache-HttpClient/4.1.1 (java 1.5)</p> <p>Response HTTP/1.1 500 Internal Server Error Server: Oracle-Application-Server-11g Oracle-Web-Cache-11g/11.1.1.6.0 (N;ecid=13472565112933034,0:1) Content-Type: application/json Content-Encoding: gzip Date: Mon, 09 Nov 2015 10:11:14 GMT Keep-Alive: timeout=5, max=999 Content-Language: en Connection: close X-Powered-By: Servlet/2.5 JSP/2.1 Content-Length: 115</p> <p>[{"status":500,"code":"General Error","message":"Unparseable date: \\supplementalinfos\\", "details":null}]</p> <p>Request GET https://psur-repo-test.eudra.org/psur-rs/public//procedures/noneusa/BE//psurs?limit=0&offset=0 HTTP/1.1</p>

ID	Component	Description	Workaround/Comment
<u>PSUR-456</u>	API	Unparsable Date Error for Non eu Supplemental info & Lookup related doc	<p>Send a request for Get Non eu Supplemental info / Lookup related doc</p> <p>List Supplemental info -- Country - Blank Datalock point - 2014-12-01</p> <p>Lookup related doc country - blank datalockpoint - 2015-09-06 documentid - 17755</p> <p>request GET https://psur-repo-test.eudra.org/psur-rs/public//procedures/noneusa//2014-12-01/supplementalinfos HTTP/1.1 Accept-Encoding: gzip,deflate Authorization: Basic d2FsbGFjZW06UGFzc3dvcmQx Accept: application/json Host: psur-repo-test.eudra.org Connection: Keep-Alive User-Agent: Apache-HttpClient/4.1.1 (java 1.5)</p> <p>response HTTP/1.1 500 Internal Server Error Server: Oracle-Application-Server-11g Oracle-Web-Cache-11g/11.1.1.6.0 (N;ecid=7422098413401333,0:1) Content-Type: application/json Content-Encoding: gzip Date: Fri, 06 Nov 2015 16:52:29 GMT Keep-Alive: timeout=5, max=999 Content-Language: en Connection: close X-Powered-By: Servlet/2.5 JSP/2.1 Content-Length: 115</p> <p>[{"status":500,"code":"General Error","message":"Unparseable date: \"supplementalinfos\"","details":null}]</p>

ID	Component	Description	Workaround/Comment
<u>PSUR-449</u>	API	Medicinal Products are always shown as null in Get Procedure resource response for all valid 32 countries	Get Procedure resource does not return the associated medical products in the response.
<u>PSUR-382</u>	Delivery File UI	Create Delivery Page - Email address validation is weak	<p>Issues:</p> <ol style="list-style-type: none"> 1. Special characters are allowed within the local part of the email address e.g - tahir&lone@example.com 2. Special characters are allowed within the hostname of the email address e.g - tahirlone@exam^ple.com 3. any value is allowed within the TLD (Top Level Domain) of the email address e.g - tahirlone@example.comnjsndjfnndfwnfjnerjf
<u>PSUR-378</u>	Deliver File UI	EMA Routing and Application Routing fields can overlap	EMA Routing and Application Routing fields can overlap
<u>PSUR-368</u>		Exceeding file limit produces inconsistent messages in IE 9,0 and Chrome	<p>When a PSUR or supplementary info submission file is uploaded via the gateway.. it creates a copy under your profile folder: "C:\Users\lonet\.cyclone\backup\TESTWT2"</p> <p>This has the effect of growing profile size and slowing down PC.. eventually on EMA domain, users are requested to delete their files.</p>
<u>PSUR-361</u>	NCA UI	Select a 'Date From' value also updates the 'Date From' field with same value	Applies to: Non-EU Search and EU Search
<u>PSUR-341</u>		Product (MAH) field is only tool tipped for 5 seconds and it not possible to copy values from this column	Product (MAH) field is only tool tipped for 5 seconds and it not possible to copy values from this column

ID	Component	Description	Workaround/Comment
<u>PSUR-339</u>	Delivery File UI	Adding a 2nd CAP eCTD product does not give a warning message immediatley as per behaviour in v1.21	The system allows launching a search for 2nd product when eCTD and CAP product is selected. The error message should pop up earlier, i.e. immediately if second eCTD product is being searched if CAP is already selected. The error is only triggered after the 2nd product is selected"
<u>PSUR-325</u>		Exceeding file limit produces inconsistent messages in IE 9,0 and Chrome	Exceeding file limit produces inconsistent messages in IE 9,0 and Chrome "An error occured during upload... [{"status":413,"code":"File Copy Failure","message":"Maximum size limit for upload is exceeded","details":null}]"

ID	Component	Description	Workaround/Comment
<u>PSUR-320</u>	NCA UI	Uploading a file for PAR or UAR in a format other than ZIP file (format for 1st upload) causes issues	<p data-bbox="958 252 1424 284">!!! Issue migrated from ClearQuest !!!</p> <p data-bbox="958 331 2085 395">Uploading a file for PAR or UAR in a format other than ZIP file (format for 1st upload) causes issues</p> <p data-bbox="958 595 1173 627">Recreation Steps:</p> <ol data-bbox="958 746 1756 1074" style="list-style-type: none"> <li data-bbox="958 746 1621 778">1. Upload a PSUR associated with a procedure number <li data-bbox="958 818 1615 850">2. Upload a PAR in zip format for a procedure number <li data-bbox="958 890 1675 922">3. Upload a UAR in doc format for same procedure number <li data-bbox="958 962 1756 994">4. Now do a search for the procedure number and down the UAR. <li data-bbox="958 1034 1167 1066">5. Open the UAR <p data-bbox="958 1193 2074 1257">UAR is in zip file format, this cannot be unzipped and cannot be renamed to a .doc file and then opened.</p> <p data-bbox="958 1377 1406 1409">Data with issue in Test environment:</p> <p data-bbox="958 1457 1279 1489">PSUSA/00000015/201504</p> <p data-bbox="958 1528 1794 1560">https://docs-test.eudra.org/webtop/drl/objectId/0b0142b281b1f400</p>

ID	Component	Description	Workaround/Comment
PSUR-297		Different behaviour of search fields when typing search criteria and hitting return	<p>In EU SA search;</p> <p>If I start typing the procedure number '0000' and press enter, without selecting anything from the dropdown the first value from the list is selected even though none of the items in the dropdown list is highlighted ♦ seems like a bug as this doesn't happen when I do the same in the MAH field (obviously not with zeros but MAH names or part of name)</p> <p>MAH name type the text (e.g glax) and list appears, if I press enter, nothing happens</p> <p>In procedure number field typed 0000 and press enter first procedure in list is selected</p> <p>behaviour on clicking enter/return should be same for all fields</p>
PSUR-295	Delivery File UI	Submission Not required Pop-up error	<p>Pop-up error message during the selection of products for a procedure.</p> <p>It could be as a consequence of generics not included in the procedure ♦ if this is indeed the case perhaps the wording needs to be amended to make it more clearer to the user what the problem is.</p>
PSUR-279	NCA UI	Assessment report, comments not displayed in search if user who submitted them does not exist in DREAM	

Version 01.04.00 (Release Date: 14 Oct 15)

What's New

This release provides change requests as prioritised by the PSUR Repository Project Advisory Group in Jul 15.

Version 01.04.00 of the PSUR Repository is released combined with version 03.03.05 of the eSubmission Gateway File Handler.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect Fix
37165	Delivery File UI	Create Delivery File - additional filters for generic products - CR linked to 37709 - Amend the product search functionality
38454	Delivery File UI	Capture contact email address when creating an XML delivery file
35231	Delivery File UI	De-duplication of PSURs in cases where the same PSUR would need to be sent multiple times as e.g. it is part of multiple lifecycles.
38118	Delivery File UI	Problems locating all trade names due to language differences
36723	Notifications	Amend the contents of notification: "List of PSURs submitted for procedure"
35873	NCA UI	UI Search form: Add procedure number to the quick search field at top of form
39017	eSub GW	The PSURs for WHO need to be accepted using the filenaming convention instead of the delivery file mechanism
38080	Delivery File UI	Fixed issue: Unexpected deselection of rows in the product table of the prepare screen
38518	NCA UI	Fixed issue: Non-EU search screen: Unable to apply filter on 'Date Received' column
38849	Notifications	Fixed issue with question mark showing for some characters with accent
38798	NCA UI	Fixed issue where the Search Result grid always had a horizontal scroll bar even when it was not needed (IE 9.0 only).
38980	Notifications	Fixed issue where there was in certain circumstances a broken subject line for the notifications

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 28 open defects listed, none are of level critical or severe.

ID	Component	Description	Workaround/Comment
38080	Delivery File UI	Unexpected deselection of rows in the product table of the prepare screen	<p>Example scenario:</p> <ol style="list-style-type: none"> 1/ in the prepare screen 2/ select product with short name "ORLISTAT RATIOPHARM", this returns K rows. 3/ in the country column header filter with "FI"; this leaves M rows. 4/ select all rows matching the filter (by selecting them either individually or with the select-all feature); M rows have been selected 5/ remove the country column header filter 6/ the table indicates that M rows have been selected 7/ in the country column header filter with "DE"; this leaves N rows. 8/ select all rows matching the filter (by selecting them with the select-all feature); N rows have been selected 9/ remove the country column header filter 10/ the selection of the rows with country="FI" has been cleared. <p>Notes:</p> <ul style="list-style-type: none"> - this may cause the risk of the user submitting incomplete data if he does not do a final check of the rows selected before creating the delivery file. - if at step 8 the rows are selected individually then there is no issue.
38138	NCA UI	Different behaviour of search fields when trying search criteria and hitting return	<p>In EU SA search:</p> <p>If I start typing the procedure number '0000' and press enter, without selecting anything from the dropdown the first value from the list is selected even though none of the items in the dropdown list is highlighted – seems like a bug as this doesn't happen when I do the same in the MAH field (obviously not with zeros but MAH names or part of name)</p> <p>MAH name type the text (e.g glax) and list appears, if I press enter, nothing happens</p> <p>In procedure number field typed 0000 and press enter first procedure in list is selected</p> <p>behaviour on clicking enter/return should be same for all fields</p>
38494	NCA UI	Uploading a file for PAR or UAR in a format other than ZIP file (format for 1st upload) causes issues	
38507	NCA UI	Exceeding file limit produces inconsistent messages in IE 9,0 and Chrome	<p>IE 9.0 :</p> <p>"An error occurred during upload... [{"status":413,"code":"File Copy Failure","message":"Maximum size limit for upload is exceeded","details":null}]"</p> <p>Chrome:</p> <p>"File size cannot be more than 50MB"</p>

ID	Component	Description	Workaround/Comment
38652	Delivery File UI EMA Admin UI	Adding a 2nd CAP eCTD product does not give a warning message immediately as per behaviour in v 01.02	
38656	NCA UI	Product (MAH) field is only tool tipped for 5 seconds and it not possible to copy values from this column: Product (MAH) field is only tool tipped for 5 seconds and it not possible to copy values from this column.	
38800	NCA UI	Attempting to upload a PAR or UAR document where the previous version is locked... user is not informed of error (IE9.0 only)	
38801	NCA UI	Comments field on Upload page can have its size adjusted in chrome but not IE 9.0.	
38876	NCA UI	Select a 'Date From' value also updates the 'Date From' field with same value. Applies to: Non-EU Search and Eu Search Page	
38164	Delivery File UI	Inconsistency between chosen products (those included in PSUSA dossier) during the creation of xml delivery file and content of dossier itself. Using PSUR repository, applicants often do not select all products that should be added to xml delivery file.	The solution that will be implemented in the next version is: In order to improve the quality of xml comparing to content of submissions, the message should appear to inform the user to mark/add all product that are mentioned in content of the dossier submitted..."

ID	Component	Description	Workaround/Comment
38707	NCA UI	Upload a comment does not always upload into Dream when a comment has been uploaded previously by the same user during the same session.	Reload the Upload page
38751	Delivery File UI	User expectation: For multiple NeES NAP products, submission would be as one consolidated package – as one sequence (hence creation of one .xml) - and so there would be only one Sequence Number, rather than one per product	This issue is still in investigation.
38888		Using Firefox only: Date from and date to calendar popup misaligned.	
39015	eSub GW	When a PSUR or supplementary info submission file is uploaded via the gateway, it creates a copy under your profile folder. This has the effect of growing profile size and slowing down PC. A better behaviour would be: After successful upload, the staging folder file created under user profile should be removed.	Manually clean up the profile folder regularly.

ID	Component	Description	Workaround/Comment
39092	Delivery File UI	<p>Email address validation is weak:</p> <ol style="list-style-type: none"> 1. Special characters are allowed within the local part of the email address e.g - tahir&lone@example.com 2. Special characters are allowed within the hostname of the email address e.g - tahir_lone@example.com 3. any value is allowed within the TLD (Top Level Domain) of the email address e.g - tahir_lone@example.comnjsdjfnndfwnfjnerjf 	
39194	EMA Admin UI	Field Labels with more than 1 word values on the Prepare submission are not correctly capitalised	This is a cosmetic issue that will be fixed in a next release.
39197	Delivery File UI	In the product selection of the prepare screen, the products listed should have their pr_product.authorisationstatus value in {1, 2, 8, 9}, products with other values must be filtered out from the selection.	Note that this issue only applies to the non-eu single assessment product selection.

ID	Component	Description	Workaround/Comment
39200	Delivery File UI	Product Selection - CAP Product selected and saved produced validation which clears the EMA number of its default value	<p>Recreation steps:</p> <ol style="list-style-type: none"> 1. Open https://psur-repo-test.eudra.org/psur-ui/prepare/submission.html 2. Select values: regulatory activity: PSUR; Submission Deadline: <Today Date>; EMA Routing ID: ESubTest; Applicant Routing ID: TESTWT2; Contact email: Valid Email Address; Submission Format: eCTD 3. Enter Procedure number such as 'PSUSA/00001967/201509' 4. Create Sequence, select CAP products 5. Now press Save. <p>Expected behaviour:</p> <ul style="list-style-type: none"> Product Selection window is not closed. Sequence Number field and associated label is highlighted in RED. EMA Number field and associated label is highlighted in RED. <p>Actual behaviour:</p> <ul style="list-style-type: none"> Product Selection window is not closed. Sequence Number field and associated label is highlighted in RED. EMA Number field is not highlighted but its default value of 'EMEA/H/C' is blanked out. <p>This is a cosmetic defect that will be fixed in the next release.</p>
39213	EMA Admin UI	Submission downloads can be suspected by Chrome to be dangerous	<p>Download repeatedly a number of Submission for the same procedure number (logged in as EMA Admin). Eventually, possibly on the 7th or 8th attempt, Chrome will warn user: "psur-repo-document.zip is not commonly downloaded and could be dangerous." This message can be ignored.</p>

ID	Component	Description	Workaround/Comment
39220	Delivery File UI EMA Admin UI	Once validation is triggered on the 'Sequence Number' field, entering values of length less than 4 trigger validation message	<p>Recreation Steps:</p> <ol style="list-style-type: none"> 1. Open Browser and goto https://psur-repo-test.eudra.org/psur-ui/prepare/submission.html 2. Enter a procedure number with associated products 3. Click Create Sequence 4. Select at least 1 product 5. Enter 4 char alpha values for the Sequence Number and press 'Save changes' button Message presented: "*Sequence number must be 4 digit number." 6. Now blank the sequence field. Message is not present anymore but sequence field and label is RED. 7. Enter 1 integer character Expected: no message should be presented as user is entering in valid permitted characters. Actual: Message presented: Sequence number must be 4 digit number. <p>Usability issue. This will be fixed in the next release.</p>
39260	Delivery File UI	Page zoom affects positioning of 'Application Routing ID' field on delivery page.	<p>Note :</p> <p>Not an issue on IE 9.0 Chrome - 67% Zoom issue manifests Firefox - 67% Zoom issue manifests</p>

ID	Component	Description	Workaround/Comment
39294	Delivery File UI EMA Admin UI	Adjusting Page zoom can cause the cells and column headers to go out of line	<p>Steps to recreate:</p> <ol style="list-style-type: none"> 1. Open browser and goto https://psur-repo-test.eudra.org/psur-ui/prepare/submission.html 2. Enter a proc number. 3. Click 'Create Sequence' 4. Select some products, enter sequence number and if required the EMA number. Click 'Save Changes' button 5. Now adjust page zoom (e.g - from 100% to 90%) 6. Open the Sequence for editing. 7. Slide the horizontal scroll bar <p>Actual: Adjusting Page zoom can cause the cells and column headers to go out of line</p> <p>Expected: Adjusting Page zoom does not affect the alignment of the cells and column headers to go out of line</p> <p>Usability issue. Will be fixed in the next release</p>
39327	Notifications	Products.xlsx column of 'MRP/DCP or CP Authorisation number' is confusing.	<p>From reading the column header: "MRP/DCP or CP Authorisation number (if not available then insert not available)" Blank values are expected for listed products but instead the text "not available"</p>
39332	Delivery File UI	In certain circumstances: SQL error when opening the 'create sequence' product selection window.	Most likely only occurs when the number of products in scope is large (e.g. 2374)
39335	Delivery File UI	In certain circumstances, substances are listed duplicatively in the selection window.	Cosmetic defect. Will be fixed in a next release.

ID	Component	Description	Workaround/Comment
39337	Delivery File UI	The system allows to add 2 different CAP products without error message. The error is only displayed when proceeding to create xml delivery file. Should not allow to close the sequence window.	Usability issue. Will be fixed in the next release.
39341	NCA UI	Duplicate suggestions when entering active substances in search and when any of the suggested values are selected.. no associated procedures are returned in the results.	Issue with data in the test environment. To be closed after go live of v 01.04
39375	DREAM	Documents added through WebTop and added to Core Master File now always found	<p>For a given procedure P:</p> <ol style="list-style-type: none"> 1- Create a document X which stands for a PRAC Recommendation and add it into a folder with a name different from '05 PRAC recommendation'; 2- Add it to the CMF of the product; 3- Link document X to the folder '05 PRAC recommendation'; <p>In the PSUR Repository search screen:</p> <ol style="list-style-type: none"> 1- Enter the procedure number for procedure P; 2- select the document type 'PRAC Recommendation'; <p>Expected: the document is returned. Actual: the document is not returned.</p> <p>This scenario is not supported by the system. We need to assess whether there is a business case to invest in this.</p> <p>The rationale for this is: emea_primary_folder_path will be created when you create an objects for the 1st time and it will not change, it is not recommended to use it as if the object is moved to another location emea_primary_folder_path won't get updated.</p>

Version 01.03.00 (Release Date: 06 Aug 15)

What's New

This release provides change requests as prioritised by the PSUR Repository Project Advisory Group in Apr 15.

Version 01.03.00 of the PSUR Repository is released combined with version 03.03.02 of the eSubmission Gateway File Handler.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect
35232	NCA UI Notifications	Information regarding silent adoption/plenary discussion in AR upload screen: At the time of circulation of the Assessment Report and/or comments the PRAC Rapporteur needs to confirm whether the report should be discussed at the PRAC plenary or whether it will be silently adopted. There are also occasions when it is necessary to highlight that plenary discussion is needed with the circulation of the Preliminary Assessment Report (PAR). This is currently done via email and picked up by the Procedure Manager (PM) and PRAC Secretariat. With the use of repository this information is lost as the AR is no longer circulated via email. The requirements are: <ol style="list-style-type: none">1. Allow the submitter of any assessment report and /or comment to provide additional information during the upload stage.2. Include the additional information in the relevant notifications. The final requirements are agreed in document "EMA/115202/2015".
35508	NCA UI	Searching with Submission Date Criteria returns wrong results: From the PSUR web app, search for PSUR documents with submission date between 10-9-2014 and 11-9-2014. Documents from 10/9 - 12/09 were returned.
36959	NCA UI	Non EU Upload Search by Authorisation Number: For Non-EU document upload add extra field to search by - Authorisation Number as DLP not always known or there could be many DLP's returned in list. This has been implemented by adding an "Upload" button on the "Search" screen.
37038	NCA UI	Insufficient file upload checks: Additional file upload checks on size and type have been added. 1/ File size limit: the files that can be uploaded via the upload page (EU or Non-EU) are limited to 50MB. A file bigger than that will cause a failure of the upload and an error to be returned to the user.

ID	Component	Brief Description of the CR or Defect
		<p>2/ File type checking: the Repository now limits the types of files that can be uploaded. A file with a different type than those below will cause a failure of the upload and an error to be returned to the user. The file types as per their IANA types are:</p> <ul style="list-style-type: none"> • PDF • MS Excel • openxmlformats-officedocument.spreadsheetml.sheet • MS Outlook • MS Powerpoint • MS Word • openxmlformats-officedocument.wordprocessingml.document • openxmlformats-officedocument.presentationml.presentation • zip
37451	NCA UI	<p>Additional search criteria needs to be provided on the non-EU PSUR and supplemental info search screen.: As a result of discussions with PRAG, it has been agreed that the users need to be able identify as far as possible specific PSURs that have been submitted for their country.</p> <p>This will facilitate the users and allow them to only download certain PSUR submissions they need to assess.</p> <p>The final requirements are agreed in document "EMA/269966/2015".</p>
37709	Delivery File UI EMA Admin UI	<p>Amend the product search functionality - 1: Relax the rules for eCTD submissions that restrict one product per submission.</p> <p>The final requirements are agreed in document "EMA/278059/2015"</p>
38071	NCA UI	<p>Document download file extensions - outlook file: Defect/CR 37038 introduced the ability to prevent certain file extensions and detect when a file extension is incorrect such as an exe re-named a docx. However, now that search/download has been fixed in RC2 it has been discovered that when downloading some of these files the file extensions are incorrect making it impossible to open the file.</p>
38076	NCA UI EMA Admin UI	<p>After session time out possible to select prepare submission: Login as an EMA user and allow session to time out. Then click Prepare Submission - User is taken to the prepare submission screen but not the one for EMA users. the standard external prepare submission screen.</p> <p>If session has timed out on clicking Prepare submission user should get same time out message as they would on trying to select any other functionality and be taken back to the login screen.</p>
38078	Delivery File UI NCA UI EMA Admin UI	<p>Footer of the page can hide information in some cases: There are cases where the footer of the page "© European Medicines Agency PSUR 1.2.0-RC2" can hide the content of a drop down no matter the size of the window. Footer should not be on top of other elements.</p>
38081	Notifications	<p>Legal Basis is truncated and does not show useful: Legal Basis is truncated to only 15 characters which does not show much useful information; no truncation is needed. Also product names are truncated, so remove truncation there and see how to accommodate best in the HTML table currently in place.</p>
38109	NCA UI	<p>Upload comment - file name from previous still displayed after subsequent uploads: Attempted to upload an invalid comment file (a .exe renamed a .doc). The system correctly prevented the upload. Then uploaded two further valid comment .doc files successfully but for some reason the invalid file name is still displayed on the screen.</p>

ID	Component	Brief Description of the CR or Defect
		Works successfully on chrome but fails on IE9
38147	NCA UI	Search screen fails with generic search: "When doing a search with 'rapporteur country' (e.g. France) and 'legal basis' (e.g. full appl.) there was an error message on the screen with some weird characters and very long text that was not human readable.
38158	EMA Admin UI eSubmission Process	Delivery.xml should be used one time only (This applies only to the admin functionality): When the same submission is sent twice (e.g. when a user hits the send button twice in the eSub Gateway UI), this causes the submission to appear twice in the Repository. The delivery.xml should only be used once so it should not work the second time anyway so this is a defect. Note: This applies to the delivery.xml files that are generated by an EMA Administrator through the special admin screen. It does not apply to the delivery.xml generated by Industry.
38187	Notifications	Notifications: date of submission appears wrong.: The date of submission in the notification appears wrong in the notification e-mail. E.g.: for a UAR which was received on the 22.05.2015, the notification says that the upload was on the 14.04.2015, which was the date of the preliminary report upload.
38498	NCA UI	Exceeding file limit of 47.68MB produces an unformatted warning message in IE 9.0: Exceeding file limit of 47.68MB produces an unformatted warning message in IE 9.0
38501	NCA UI	When removing a file for upload only removes the Upload/Remove/Cancel buttons: When removing a file for upload only removes the Upload/Remove/Cancel buttons and NOT the file input path
38502	NCA UI	Label for upload document success has typos: Label for upload document success has typos.
38518	NCA UI	Unable to apply filter on 'Date Received' column (go to the non-eu search screen): Unable to apply filter on 'Date Received' column.
38519	EMA Admin UI	Users with psur_repository_admin role are able to see 'Upload' button on search screen: Users with psur_repository_admin role are able to see 'Upload' button on search screen.
38520	NCA UI	Search Reset does not reset column filters (behaviour same on IE 9.0 and Chrome). This is applicable to both EU Single and Non-EU Single Assessment searches.
38527	NCA UI	Exceeding file limit when attempting an PAR upload in IE 9,0 will lock file in dream: Exceeding file limit when attempting an PAR upload in IE 9.0 will lock the file in DREAM. Not a problem with comments upload and not a problem in Chrome.
38534	NCA UI	Under certain conditions invalid file is reported as successfully uploaded on Non-EU SA upload screen.
38535	NCA UI	Active substance for an EU submission with long string value can cause the delete text icon to be misplaced in Procedure Number field
38539	Delivery File UI	Preparing Delivery File eCTD with Multiple CAP products informs user that eCTD submissions cannot have more than 1 product Actual message: "For an eCTD submission, you cannot select more than one product. Please either amend the number of products or select the correct submission format." Expected message: A correct message informing user that eCTD CAP submissions cannot have multiple products associated.

ID	Component	Brief Description of the CR or Defect
38547	NCA UI EMA Admin UI	Log Page Scroll bar for IE 9,0 and Chrome does not allow scrolling to 'Sign In' button
38062	eSubmission Process	<p>Certain PSUR submissions in eCTD format are rejected by EURS</p> <p>Issue Summary: The Gateway File Handler (GWFH) currently uses the parameters "EURDID_MAH name" to create "Dossier Titles" in EURS. As result, certain PSUR submissions in eCTD format are rejected by EURS because:</p> <ol style="list-style-type: none"> 1. EURS is unable to import submissions with duplicate/identical Sequence numbers within one dossier. 2. Non-Sequential order of submissions are rejected, as EURS is unable to handle submission imports in descending order (e.g. Seq 0003 after Seq 0010). <p>Proposed Solution:</p> <ol style="list-style-type: none"> 1. Generate a unique identifier (UID) for each PSUSA transmission upon receipt via gateway. 2. Modify/re-configure GWFH import scripts to create a dossier in EURS with following parameters (for All PSUSA submissions): EURDID_DLP_MAH_UID e.g. Dossier Title in EURS will be displayed as: 00001234_201509_Pfizer_01901ajkio09100019 <p>eCTD attributes such as Substance name, Submission Type etc. will be populated in EURS as per values from eCTD envelope.</p>
38463	eSubmission Process	Add support of ASMFs and PMFs in the transmission of working docs: Currently the working documents are emailed to NCAs only for those submissions that go into EURS (CAPs, PSUSAs). There is a need to be able to automatically send working documents for ASMFs and PMFs.
38585	eSubmission Process	<p>Remove characters not supported in windows filenames from EURS dossier name: Special characters ex (/) when used in the dossier name, cause failures in the EURS import process, since the file system does not support these characters in the creation of a folder name.</p> <p>Also, reject submission that contain unsupported characters in the filename, to avoid any processing errors or security risks.</p>
38639	eSubmission Process	Add a filter in the Gateway File Handler (GWFH) web console to allow searching on submitted files based on whether they have been imported in the PSUR repository or not.
38605	Delivery File UI	Prepare screen does not recover from selecting multiple times the same product.
38641	NCA UI	Reducing column widths for Non-EU search result grids causes columns and headers to become out of line
38658	Delivery File UI	Prepare Delivery File Page - Reset button does not clear the MAH product field
38682	NCA UI	Widening Columns does move columns to the right hand side out of view and no scroll bar is presented. Grid for document search results does not present options to adjust size as well.

ID	Component	Brief Description of the CR or Defect
38711	NCA UI	Possible to choose both silent and for plenary discussion for UAR doc type. Section 4.2 of the specification states that it should be either silent OR plenary discussion.
38715	NCA UI	In the UC for CR37451: 1/ The screen mock-up in section 5 does not show the substance in the search grid, it should however be reinstated. 2/ Also for products, one can remove the NA No. string. 3/ Add a horizontal scroll-bar for the result grid. Note: This should be done for both EU SA and Non-EU SA. 4/ For the column at the left hand side of the search grid, use the same style as for EU (see screenshot attached) Note: Can the date be formatted as all other dates in the system: DD/MM/YYYY
38719	NCA UI	Clicking a column header to amend sorting type....disables previously set sorting on other columns
38655	Delivery File UI EMA Admin UI	Warning Message of 'No Product selected' is not dismissed upon product selection

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 19 open defects listed, none are of level critical or severe.

ID	Component	Description	Workaround/Comment
38080	Delivery File UI	Unexpected deselection of rows in the product table of the prepare screen	<p>Example scenario:</p> <ol style="list-style-type: none"> 1/ in the prepare screen 2/ select product with short name "ORLISTAT RATIOPHARM", this returns K rows. 3/ in the country column header filter with "FI"; this leaves M rows. 4/ select all rows matching the filter (by selecting them either individually or with the select-all feature); M rows have been selected 5/ remove the country column header filter 6/ the table indicates that M rows have been selected 7/ in the country column header filter with "DE"; this leaves N rows. 8/ select all rows matching the filter (by selecting them with the select-all feature); N rows have been selected 9/ remove the country column header filter 10/ the selection of the rows with country="FI" has been cleared. <p>Notes:</p> <ul style="list-style-type: none"> - this may cause the risk of the user submitting incomplete data if he does not do a final check of the rows selected before creating the delivery file. - if at step 8 the rows are selected individually then there is no issue.
38138	NCA UI	Different behaviour of search fields when trying search criteria and hitting return	<p>In EU SA search:</p> <p>If I start typing the procedure number '0000' and press enter, without selecting anything from the dropdown the first value from the list is selected even though none of the items in the dropdown list is highlighted – seems like a bug as this doesn't happen when I do the same in the MAH field (obviously not with zeros but MAH names or part of name)</p> <p>MAH name type the text (e.g glax) and list appears, if I press enter, nothing happens</p> <p>In procedure number field typed 0000 and press enter first procedure in list is selected</p> <p>behaviour on clicking enter/return should be same for all fields</p>
38494	NCA UI	Uploading a file for PAR or UAR in a format other than ZIP file (format for 1st upload) causes issues	
38507	NCA UI	Exceeding file limit produces inconsistent messages in IE 9,0 and Chrome	<p>IE 9.0 :</p> <p>"An error occurred during upload... [{"status":413,"code":"File Copy Failure","message":"Maximum size limit for upload is exceeded","details":null}]"</p> <p>Chrome:</p> <p>"File size cannot be more than 50MB"</p>

ID	Component	Description	Workaround/Comment
38547		Log Page Scroll bar for IE 9,0 and Chrome does not allow scrolling to'Sign In' button	
38605		Prepare screen does not recover from selecting multiple times the same product	
38652	Delivery File UI EMA Admin UI	Adding a 2nd CAP eCTD product does not give a warning message immediately as per behaviour in v 01.02	
38656	NCA UI	Product (MAH) field is only tool tipped for 5 seconds and it not possible to copy values from this column: Product (MAH) field is only tool tipped for 5 seconds and it not possible to copy values from this column.	
38798	NCA UI	Search Result grid always has a horizontal scroll bar even when its not needed (IE 9.0 only): Note - not a problem with chrome browser	
38800	NCA UI	Attempting to upload a PAR or UAR document where the previous version is locked... user is not informed of error (IE9.0 only)	
38801	NCA UI	Comments field on Upload page can have its size adjusted in chrome but not IE 9.0.	
38876	NCA UI	Select a 'Date From' value also updates the 'Date From' field with same value. Applies to: Non-EU Search and Eu Search Page	

ID	Component	Description	Workaround/Comment
38553	Delivery File UI EMA Admin UI	NeeS submissions can select CAP products in certain situations	
38170		BR5.1 data field validation rule for max length not implemented.	
38115	Delivery File UI EMA Admin UI	<p>New Products should be added at the top of the product selection table: When a user selects a product short name in the text field then the row for that product short name is added at the end of the table. If there are many products in the table, the user may not have noticed that a product was added and even then, the user would have each time to scroll down the bottom of the table.</p> <p>Suggested improvement: when a short name is selected, then the corresponding row should be added as the 1st row of the table.</p>	
38130	Delivery File UI EMA Admin UI	Submission Not required Pop-up error: Pop-up error message during the selection of products for a procedure. It could be as a consequence of generics not included in the procedure – if this is indeed the case perhaps the wording needs to be amended to make it more clear to the user what the problem is.	
38849		Letters with accent showing question mark	

ID	Component	Description	Workaround/Comment
38751	Delivery File UI EMA Admin UI	Unique Sequence Number Required for NeeS NAP Product submission: For multiple NeeS NAP products, submission would be as one consolidated package – as one sequence (hence creation of one .xml) - and so there would be only one Sequence Number.	
38164		Inconsistency between chosen products (those included in PSUSA dossier) during the creation of xml delivery file and content of dossier itself. Using PSUR repository, applicants often do not select all products that should be added to xml delivery file.	

Version 01.02.00 (Release Date: 01 June 2015)

What's New

This release provides change requests enhancing the system and fixes defects identified after the UAT end 2014 or since the start of the pilot phase. In particular, this release provides solutions for all remaining findings from the audit carried out by PwC Luxembourg in Feb-Mar 15. Also included in this release is functionality supporting EMA to more efficiently process incoming PSURs (aka "The Business Administration Screen").

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect
36785	NCA UI	Search criteria should be trimmed from leading whitespace characters.: All input fields should be trimmed of any leading whitespace characters
35855	EMA Admin UI	Business administration screen: EMA business users should be able to add items to the repository, e.g. submissions from reconciliation or others
36151	DREAM	Access to UI for EMA PM/AST: Access the repository by EMA PM/AST.
37126	NCA UI	The date picker in the "To" date field should start from the date selected in the "From" date field.: As above.
37130	NCA UI	On the non-EU screen it is not clear which date criteria will be applied for the date range search: It would be much more useful to the user if the label inside the date fields indicated that the date relates to "submission date". So the system should display the label "Submission date from" and "Submission date to". The "Member State" label should be sentence case and it should read, "Select Member State" or the shorter version, "Select MS".
37390	DREAM	Users with no role/capabilities to use the PSUR Repository should not be allowed to log in the system: At the moment any user who can be authenticated by DREAM is allowed in the search screen of the PSUR Repository. Any further action is however denied by security over the web services. This is not a very elegant way to block unauthorised users from using the system. The ideal scenario would be that a user is denied access to the PSUR Repository if: - he does not authenticate successfully. or - he has no roles/capabilities to use the PSUR Repository.
37694	Delivery File UI	Audit finding 5: Inconsistency of the form/content of error messages displayed on the interface for delivery file creation: The errors simulated on the fields present in the interface for the delivery file creation, led to the display of different types of error messages (pop-ups, text highlighted in red) which content can sometimes be unclear (e.g. HC number vs. EMA number)
37695	NCA UI	Audit Finding 6: Query using a wrong procedure number allows retrieval of documents: Performing a query using a wrong procedure number for a specific active substance (PSUSA/0000311/201412 instead of PSUSA/00000311/201412) allowed the retrieval of all PSUR documents related to this substance regardless the validity of the procedure number. As the output of the query does not identify the error, the user will get all the documents related to the active substance under all procedures stored in the repository. The result of the query could be confusing for the user who could download by mistake a file which is not under the procedure she/he is looking for. Besides, it could also be time-consuming for the user to look for a specific document under a specific procedure number.
37696	NCA UI	Audit Finding 7: Inconsistency of the denomination "Submission date": DLP and Submission date are the two criteria that can be chosen in the drop down list to perform a query under "Date" section. If DLP refers to the Data-Lock-Point which is a field present on the EURD list, the Submission Date criteria doesn't refer to the submission deadline on which the PSUR must be submitted by the MAH as indicated in the EURD list, but it refers to the dates on which PSUR documents have been submitted to the repository. This terminology could be confusing for the user who would probably associate the submission date with the submission deadline of the EURD list.
37697	NCA UI	Audit Finding 8: Inconsistency of the error messages displayed: The error messages displayed when performing wrong queries do not highlight precisely the error made.

ID	Component	Brief Description of the CR or Defect
37706	Delivery File UI	<p>Empty pop up message displayed when EMA Number is not populated in the prepare screen:</p> <ul style="list-style-type: none"> - Select eCTD type (for CAP since it asks for the EMA product number) - Start typing a product in the product search field - Select the products desired - Do not enter any EMA product number (HC number) - All other steps to complete the form. - Generate delivery file. <p>A popup comes up with but it is blank and it should contain relevant details in order to say that the EMA product number is missing.</p>
37734	Notifications	<p>Product name in the PSURs received notification is incomplete: See example below; the name of the products is incomplete. This makes it difficult for the recipients to verify whether the list of expected products in the procedure is complete. The users will have to open each individual submission to elicit the information that is present in the notification.</p> <p>"ACIDE PARA AMINO HIPPURIQUE 0.2g/1mL, solution injectable..."</p>
37769	NCA UI	<p>Date filtering is not user friendly: In the search result table there is a discrepancy between the format for dates as shown and the format needed in order to filter by date.</p> <p>Date format as shown in search results: DD/MM/YYYY</p> <p>Date format required for the filter: YYYY-MM-DD</p>
37781	NCA UI	<p>Three character search for active substance does not work on search screen: Three character search for active substance does not work on search screen. As soon as you type 4th character results are displayed.</p>
37825	NCA UI	<p>Downloading multiple documents results in not all files being put in the zip: When the user does an EU or Non EU search and selects multiple documents to download including PSUR, Comments, and AR only the PSUR (zip files) get added to the zip. It is not a problem of only one file being put in the zip as multiple PSUR's all get put in the zip fine. It is just the AR and comments that no longer get put in the zip.</p> <p>Downloading any of the documents individually works fine.</p>
37861	Delivery File UI	<p>Empty pop-up after legal basis validation failure: There is a UI issue when reporting the negative legal basis validation message to the prepare screen.</p>
37891	NCA UI	<p>Search for other document fail when searched for just MA type</p>
37893	eSubmission Process	<p>Error when validating a delivery file with a PSUSA number that does not exist: For EU single assessment, when the delivery file contains a PSUSA number that does not exist, then the validation ends abruptly and the end user does not get a proper message back. Indeed the DLP validator is next the sequence of validators and it relies on the existence of the PSUSA number.</p> <p>Instead, if the PSUSA number is not found, then the validation should stop gracefully and return the correct error message to the end user.</p>
37974	NCA UI	<p>Pop-up error message for invalid date search data needs amending: When logged in as a viewer and running a search for EU single assessment if a date type is selected but the from to dates left blank and search is clicked the user gets a pop up error message. The first part of the error is correct but there is additional information that should not be there and it should no longer be a pop up error.</p>
37975	NCA UI	<p>Date type drop down on EU search has typo: the drop down list for date tpe contains a typo. it should be Date received (ei not ie)</p>

ID	Component	Brief Description of the CR or Defect
37989	EMA Admin UI	Business Admin Screen - Create Delivery File - Comments field error: login as an EMA user and go to create a new delivery file. select other from reason for submission. user gets comments box. on clicking generate delivery file comments field is highlighted red - assume due to the comment being too long but the user needs an error message telling them this and what the max comment length is!
37991	EMA Admin UI	EMA Admin Submission - submission date in future can be selected: When creating a delivery file as the EMA admin it is possible to select and proceed to create the delivery file for original submission date in the future. The requirements state that the submission date must not be a future date. This is the case for all the reasons for submission.
37992	EMA Admin UI	EMA admin submission typo: on the create delivery file form when logged in as an EMA user in the EMA admin section of the form EMA is spelt Ema - should be all upper case
37994	NCA UI	Search and upload not working in a specific scenario: Search for PSUR procedure number is found but on selecting document types and clicking search nothing is returned. Upload user is able to select file to upload but on clicking upload nothing happens.
37901	eSubmission Process	Produce a clear error message when there is white space detected in a part of the filename.: When there is whitespace (space character, line change etc.) in a part of the filename, the error reported back to the user is not clear enough and it produces some confusion as the user cannot easily understand what was the reason of failure.
37946		Add PSUR product information in failure notification emails: Based on Change request: emea00036831, the PSUR product information needs to be added not only in the success notification emails, but also in the failed messages sent to eCTD support.

Version 01.01.00 (Release Date: 24 March 2015)

What's New

This release provides change requests enhancing the system and fixes defects identified after the UAT end 2014 or since the start of the pilot phase.

New Change Requests Delivered and Defects Fixed in this Version

This section lists defects fixed and change requests provided that are of relevance for users. This release also contains some fixes which are not listed here as they are only relevant for the technical team supporting the system.

ID	Component	Brief Description of the CR or Defect
35863	Delivery File UI	The Create Delivery File function needs to prevent submission prior to data lock point. The same rule must apply to both the creation of the delivery file and the submission of the PSUR/Supplemental Info.

ID	Component	Brief Description of the CR or Defect
36388	Delivery File UI	UI: Create Delivery File: The label for field MRP/DCP number on the product presentation level table needs to be changed to EMEA Product number/MRP/DCP number
36510	NCA UI	Improvements to the document upload: Prevent uploading same document twice or warn if already exists: Get a warning when you are trying to upload twice a preliminary AR under the same PSUSA procedure. This will help to make clear that you have already one and you are trying to substitute it by the last one.
36606	Delivery File UI	The following text should be constantly displayed on the screen near the product selection grid: "If you cannot find one or more of your products, please ensure that your Art. 57 data is up to date. Please go to the following link for further guidance on updating Art. 57 data."
36682		Review logging level: Tests have shown that there are too many useless log messages.
36731	Delivery File UI	Allow user to filter product search results using "contains" rather than "begins with".
36742	Delivery File UI	Product data should allow filtering to exclude nullified products.
36778	Notifications	Notifications: wrong caching of EUTCT terms.
36894	eSubmission process	Improve reporting of filename convention errors to the user: 1. In case of vNees, when the dossier name does not include a number, then this should be reported back to the user. Ex: ESUBPNAHPROD_ESUBPROD_VXXXXXXX_Monepantel-mrl-extension_vNeeS_0120.zip 2. In the case that the number of filenameparts does not correspond to any known message type, the system should try to send an error message to the sender routing id (always the first part of the filename). Ex: ESUB643_ESUBPROD_001789_isoniazid_ALLIANCE_201411_psusa-0005.zip
36964	eSubmission process	Improve the error handling of the working folders email generation activity. In case of failure, an email should be sent to the support team.
36969	NCA UI	No result found message should remain on screen until user dismisses it: if a search is run and no results are found the no results found message disappears after a few seconds and it is possible the user will miss the message thus not knowing if their search has run or not. The message needs to be made into a popup that the user has to click OK to close.
36978	NCA UI	PSUR-RS upload URLs should be secured
37037		Add support for Response to worksharing submission type (WS_xxxx_supplemental-info): The filename convention is the following: ESUBPAMGEN_ESUBPROD_HC001120_Prolia_WSxxxx_supplemental-info_0125.zip
37051	NCA UI	No file upload limit.
37071	eSubmission process	EURS does not allow eCTD and NeeS submissions in the same dossier.
37100	eSubmission process	Handle zip files that do not contain physical directories: There have been cases in eSubmissions that zip files did not contain physical directories but only files that defined a directory structure solely by the path that is included in the filenames. These cases are not handled correctly and result in submissions that are expanded as a flat list of files without any directory structure.
37124	NCA UI	Date range search for non-EU search does not work
37146	NCA UI	User is shown the same message 4 times before returning to the log in screen. This defect is specific to Chrome.

ID	Component	Brief Description of the CR or Defect
37162	NCA UI	On the upload screen the sequence number is displayed as a single digit. It should be displayed as a four-digit number padded with zeros.
37176		Search screen: Rapp name list is not ordered alphabetically (a-z).
37187	DREAM	Folder '06 CHMP Opinion' is not automatically created.
35155	Delivery File UI	MAH products to which the submission relates cannot be removed once selected: Once user has added a product they cannot then remove it if it was selected incorrectly. This is specific to IE9 as on Firefox there is an X next to the product allowing the user to remove it.
35870	NCA UI	Search results are not adequate, it's difficult to see what the submission actually contains. When ticking the box next to document type the details appear below, except if multiple submissions/documents are selected, it still only shows one set of details – which basis it's selected which one? 1. On the right hand column there should be more details about the results, the active substance(s) should be shown together with the procedure number and the DPL 2. It would be good to have the details on the submission/document next to it, or under it or if that's not possible even in a list below (it doesn't matter if the page is long and has to be scrolled).
36336	NCA UI	Users with the viewer role should not have the button to upload documents.
36740	NCA UI	Currently the EU substance Search is case sensitive and requires users to make case sensitive searches in order to retrieve the full list of active substances. We should make this search case insensitive so that the full substance set becomes more easily available without requiring knowledge of the way that the description is stored in the system's database.
36776	NCA UI	All inputs for search must be treated as case-insensitive.
36777	NCA UI	Screen: Upload document for non-EU single assessment: "Find submissions" clears results if button is clicked twice: If the "Find Submissions" is clicked twice then the results grid is cleared. The only way to get the results back is to do clear one of the criteria and search again.
36781	Notifications	1/ In the subject of the comment notification, appears the country of the reporting country and not of the commenting country. 2/ In the subject of the PSUR the country name is in full instead of just using the country code
36788	NCA UI	IE9: When clicking the Logout button the user is redirected to the login page but when he pastes the following URL (for example) https://psur-repo-test.eudra.org/psur-ui/app.html#/ he goes back to the search page.
36790	NCA UI	Non EU Search, Marketing Authorisation holder cannot be selected by the drop down.
36793		User should be able to paste in the search criteria: Users should be able paste in the search criteria and then press enter to conduct the search (if all mandatory fields have been provided). The paste option can be limited to those fields that are not selection lists. This enhancement is particularly useful when users want to use the information in the notifications to conduct the search.
36797	NCA UI	Clicking on the column headings in the main results grid sorts the results by the column the user clicked on. This is very useful feature for sorting large result sets. However, users will not know about this because there is no indicator that results can indeed be sorted.
36798	Delivery File UI	The grid that displays the full products at presentation level lets the user can hide a column but then he cannot unhide it.

ID	Component	Brief Description of the CR or Defect
36873	eSubmission process	Enforce proper file format detection in the system.: It came out as a security precaution that the system must perform a real file type check.
36979	NCA UI	Placeholders for non eu search on ie9 was not working.
37115	NCA UI	When downloading a supplemental info file the file extension is removed (ZIP). It is present on the file in DREAM.
37129	NCA UI	Display a more informative message than "Error!" in non-EU date range search if only one date is provided.
37149	Delivery File UI	Unable to submit supplemental info after submission deadline: It is not possible to create a delivery file for supplemental info after the submission deadline has passed. The submission deadline rule should on be applied for first submission.

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There is in total 1 open defect listed.

ID	Component	Description	Workaround/Comment
36785	NCA UI	Search criteria should be trimmed from leading whitespace characters.: All input fields should be trimmed of any leading whitespace characters	

Version 01.00.01 (Release Date: 28 January 2015)

What's New

This release fixes an intermittent issue with IE9 caused by caching.

New Change Requests Delivered and Defects Fixed in this Version

ID	Brief Description of the CR or Defect
36984	There is an intermittent issue with IE9 caused by caching. This can cause the Procedure Number to not return any results and the Document Type field to only show one option rather. As a work around it is possible to open a private browsing session in IE9 (open a New Tab and click on InPrivate Browsing link at the bottom of the tab. This will open a new IE9 window, navigate the PSUR URL as normal

Known Issues

This section lists the known defects with reference to the formally approved set of requirements.

Change requests are not listed here.

There are in total 13 open defects listed, of which 0 are classified as "Critical", 0 as "Severe", 9 as "Important" and 4 as "Minor".

ID	Component	Description	Workaround/Comment
36978	NCA UI	Upload URLs should be secured	Currently all URLswith format "/procedures/**" are allowed using both "viewer/contributor" role. Actually "upload" URLs should be allowed only for user with "contributor" role.
36742	NCA UI	Product data should allow filtering to exclude nullified products.	
36779	NCA UI	URL can be copied and pasted and user does not have to login again	It is possible to copy the URL when logged in. After having logged out a session and then pasted that URL into another browser session, the system allows you access without logging in again. When pasting a URL, the user should be returned to login. If going between IE9 and Firefox this does not happen - user gets session expired message.
36336	NCA UI	Users with the viewer role should not have the button to upload documents.	
36648	NCA UI	Type ahead character limit must be 4 and not 3	
36740	NCA UI	Make EU Substance Search case insensitive	Currently the EU substance Search is case sensitive and requires users to make case sensitive searches in order to retrieve the full list of active substances. We will make this search case insensitive so that the full substance set becomes more easily available without requiring knowledge of the way the description is stored in the system's database.

ID	Component	Description	Workaround/Comment
36776	NCA UI Delivery File UI	All inputs for search must be treated as case-insensitive.	
36777	NCA UI	Screen: Upload document for non-EU single assessment - "Find submissions" clears results if button is clicked twice	If the "Find Submissions" is clicked twice then the results grid is cleared. The only way to get the results back is to do clear one of the criteria and search again.
36790	NCA UI	Non EU Search, Marketing Authorisation holder cannot be selected by the drop down	In Non EU Search, the Marketing Authorisation holder cannot be selected by the drop down. Although the search is done properly and the drop down is populated correctly, the user cannot select any entry.
36781	Notifications	Notifications COMMENTS: the subject contains the country of the rapporteur instead of the country of the commenting country	1/ In the subject of the comment notification, the country of the rapporteur country appears instead of the commenting country 2/ In the subject of the PSUR the country name is in full instead of just using the country code
36788	NCA UI	IE9: logout incomplete	When the user presses the Logout button, they are redirected to the login page but when then pasting the following URL (for example) https://psur-repo-test.eudra.org/psur-ui/app.html#/ , the user is taken back back to the search page, which is most unexpected.
36798		The grid that displays the full products at presentation level lets the user can hide a column but then cannot unhide it!	<ol style="list-style-type: none"> 1. Search for a product short name 2. Select a product to display the full list in the grid. 3. Choose a column to hide by clicking the down arrow and click "hide column". (see screens attached) 4. Impossible to unhide the column.
36979		Placeholders for non eu search on ie9 was not working	Placeholders for non EU search on IE9 are not working. Also changed placeholders for submission date in prepare and search screen.

Version 01.00.00 (Release Date: 26 January 2015)

What's New

This is the first release of the PSUR Repository and provides the "Auditable Functionalities" as per the EMA Management Board decision in December 2013. This version will be used during the pilot phase. Subsequence next versions will add more functionality in agreement with the various NCA bodies and Stakeholder groups.

The main visible components of this release are: NCA UI (see table above) version 00.03.06 and Delivery File UI (see table above) version 00.03.06.

New Change Requests Delivered and Defects Fixed in this Version

As release 00.03.06

Known Issues

As release 00.03.06

Version 00.03.06 (Release Date: 6 January 2015)

What's New

This release fixes most of the remaining defects found during the final round of System Test and UAT completed in 2014.

New Change Requests Delivered and Defects Fixed in this Version

ID	Brief Description of the CR or Defect
36063	Comment Notification Issues
36358	ZIP file was not unzipped completely by Documentum Java Server Method
36372	Upload of document for Non EU SA (allow for filtering of DLP after selection of country)
36386	Notification: failure in EUTCT causes notifications after deadline not to be sent.

ID	Brief Description of the CR or Defect
36443	UI: PSUR Download when 3 or more procedures selected in down loads incorrectly
36501	Amend text in existing notifications
36617	Legal Basis Validation: the flag for legal basis in the EURD list is not taken into account.
36648	Type ahead character limit must be 4 and not 3
36660	PSUR/SUPP INFO submission fails with substances having invalid character for folder naming
36661	Search table: come up with more sensible names for the document types.
36696	Cannot upload new assessment report on DB down or out of memory
36716	Legal Basis validation rejects a submission for a procedure where require legal basis is 'Y'
36063	Comment Notification Issues

Known Issues

There is an intermittent issue with IE9 caused by caching. This can cause the Procedure Number to not return any results and the Document type field to only show one option rather. As a work around it is possible to open a private browsing session in IE9 (open a New Tab and click on InPrivate Browsing link at the bottom of the tab. This will open a new IE9 window, navigate the PSUR URL as normal)

This section lists the known defects with reference to the formally approved set of requirements. The next releases of the software will address the defects listed here in a prioritised fashion.

Change requests are not listed here.

There are in total 13 open defects listed, of which 0 are classified as "Critical", 0 as "Severe", 9 as "Important" and 2 as "Minor", and 2 as "Enhancement".

ID	Component	Description	Workaround/Comment
35508	Search	Searching with Submission Date Criteria returns wrong results	All other search criteria can be used instead to find required documents
36336	Website	Users with the viewer role should not have the button to upload documents.	

ID	Component	Description	Workaround/Comment
36648	Website	Type ahead character limit must be 4 and not 3	
36731	Create Delivery File	Allow user to filter product search results using "contains" rather than "begins with"	
36740	Search	Make EU Substance Search case insensitive	
36742	Search Submit	Product data should allow filtering to exclude nullified products.	
36776	Search Website	All inputs for search must be treated as case-insensitive.	
36777	Search	Screen: Upload document for non-EU single assessment - "Find submissions" clears results if button is clicked twice	
36781	Search	Notifications COMMENTS: the subject contains the country of the rapporteur instead of the country of the commenting country	
36785	Search	Search criteria should be trimmed from leading whitespace characters.	
36788	Website	IE9: logout incomplete	
36790	Search	Non EU Search, Marketing Authorisation holder cannot be selected by the drop down	
36798	Create Delivery File	The grid that displays the full products at presentation level lets the user can hide a column but then cannot unhide it!	

Version 00.03.05 (Release Date: 15 December 2014)

What's New

This release fixes most issues discovered during the second week of the user acceptance testing with Industry and NCAs and some issues of release 00.03.03.

New Change Requests Delivered and Defects Fixed in this Version

ID	Brief Description of the CR or Defect
36080	Duplicate submission leads to data being overwritten.
36123	Legal basis error message is incorrect and is incorrectly formatted.
36340	UI Presentation: Order of type-ahead and drop downs to be sorted
36371	The background colour for selected items should be slightly darker.
36427	Some Notifications need to be sent to ALL Member states
36444	Investigate/Improve performance of active substance search
36453	Supplemental Info: Notification is not sent.
36458	c_data_lock_point should be mandatory,c_procedure_number should not be mandatory in documentum
36460	UI: Search results are missing the Submitter Country - Column is blank
36624	Folder linking is not working when a PSUR is submitted. requires manual intervention

Version 00.03.03 (Release Date: 8 December 2014)

What's New

This release fixes most issues discovered during the second week of the user acceptance testing with Industry and NCAs and some issues of release 00.03.04.

New Change Requests Delivered and Defects Fixed in this Version

ID	Brief Description of the CR or Defect
35357	XSD Contains too much information
36144	System rules regarding the order in which assessment reports should be uploaded have not been implemented
36244	Sentence case in messages
36333	Upload screen for non-EU assessment (screen should display active substances)
36336	Users with the viewer role should not have the button to upload documents.
36374	Non EU SA notifications
36382	Product list is not updated in search details section when a different procedure number is selected
36425	Duplicate non eu entries in procedure result list
36435	UI: Create Delivery File - Possible to add multiple product as a NeeS then change to eCTD for Non Eu
36476	PSUR Repository: Add constraints to the data model. DB constraints
36599	Error message shown in the search screen

Version 00.03.02 (Release Date: 18 Nov 2014)

What's New

This release fixes most issues discovered during the first week of the user acceptance testing with Industry and NCAs and some issues of release 00.03.01.

New Change Requests Delivered and Defects Fixed in this Version

ID	Brief Description of the CR or Defect
36141	The procedure number field on the create delivery file form did not appear to be ordered correctly. It is now ordered by procedure number then DLP date.
36179	When a file was uploaded through the UI/API the filename went in full (i.e. with the extension) into the property 'object_name'. When a file was uploaded through WebTop the filename was stripped from its extension and went as well into 'object_name'. So when a file uploaded with WebTop was downloaded with the UI then it came without an extension, which was not right. Fix: The upload should strip the filename extension, so that it reproduces what WebTop does.

ID	Brief Description of the CR or Defect
36209	The information shown in the Details section of the search screen, when selecting a PSUSA showed too much information. The details shown were indeed for each presentation in the submission but there was some repetition that needed to be filtered out. The product names as displayed are now unique.
36290	UI: Create Delivery File - Reset Button now not resets all fields
36294	Some long drop down lists were hidden by other components and were not completely visible
36337	Autocomplete dropdowns can now be left work with [Tab key].
36347	For single NAP submission the folders for country and data lock point in the Repository were assigned the wrong access rights.
36356	Upload non-EU Documents: Search results out of alignment in the table.
36364	The submission deadline should be inclusive and not exclusive.
36366	Issues in downloading previously uploaded documents
36367	Search screen did not reset the selection of individual documents
36369	File download could not cope well with files with white space in the filename.
36374	Non-EU SA notifications: The subjects do now mention the country for which the submission is targeted.
36344	Technical change (Organise front-end code, limit code duplication, minify)

Known Issues

This section lists the known defects with reference to the formally approved set of requirements. The next releases of the software will address the defects listed here in a prioritised fashion.

Change requests are not listed here.

There are in total 12 open defects listed, of which 0 are classified as "Critical", 2 as "Severe", 8 as "Important" and 2 as "Minor".

ID	Component	Description	Workaround/Comment
36358	NCA UI	ZIP file was not unzipped completely	This intermittent problem can result in a file being full processed and available in the PSUR Repository but still not findable via the NCA UI extract PSUR job failed at unzipping a PSUR submission. If you suspect encountering this situation, contact the tech team with reference of the ID of this issue.

ID	Component	Description	Workaround/Comment
36386	Notifications	Notification: failure in EUTCT causes notifications after deadline not to be sent.	
36333	NCA UI	Upload screen for non-EU assessment: Screen should display active substances.	Although the submissions are listed no active substances are listed.
36382	NCA UI	Product list is not updated in search details section when a different procedure number is selected	
36080	eSubmission process	Duplicate submission leads to data being overwritten.	
36144	NCA UI	System rules regarding the order in which assessment reports should be uploaded have not been implemented	<p>The expected behaviour is:</p> <ol style="list-style-type: none"> 1. If a preliminary report for the selected procedure number does not exist then system selects preliminary assessment. This selection cannot be changed by the user. 2. If a preliminary report for the selected procedure number exists then the user can only select preliminary assessment report or "Comments on AR". 3. If an updated assessment report exists then the user can only select "Updated AR" or "Comments on AR".
36244	All	Sentence case in messages	Certain messages are not written in correct sentence case.
36336	NCA UI	Users with the viewer role should not have the button to upload documents.	

ID	Component	Description	Workaround/Comment
36340	All	UI: Order of type-ahead and drop downs to be sorted	The order or product (and possibly) substance is not currently alphabetical.
36372	NCA UI	Upload of document for Non-EU SA: Allow for filtering of DLP after selection of country	The upload of non-EU SA should enforce first the selection of the country and then allow a type-ahead or similar for the DLP selection. This would greatly improve the speed and usability of the upload for non-EA SA. Indeed at the moment, the user can enter any date, which is error prone.
36241	All	Type-ahead and minimum number of characters to trigger the search	The current type-ahead for products (and other fields) is triggered after at least 4 characters have been entered. This would be a problem if the product to look for has only 3 characters.
36371	NCA UI Delivery File UI	The background colour for selected items should be slightly darker.	

Version 00.03.01.01 (Release Date: 14 Nov 2014)

What's New

This release fixes issue 36288.

New Change Requests Delivered and Defects Fixed in this Version

ID	Brief Description of the CR or Defect
00036288	Product search error in specific navigation scenario

Known Issues

There are in total 13 open defects listed, of which 0 are classified as "Critical", 0 as "Severe", 5 as "Important" and 8 as "Minor".

See section "Known Issues" of release 03.01.01, minus defect 00036288.

Version 00.03.01 (Release Date: 12 Nov 2014)

What's New

This version of the PSUR Repository delivers all functionality as per document "PSUR Repository functionalities to be audited (EMA/681848/2013)", endorsed by the EMA Management Board, the Pharmacovigilance Risk Assessment Committee and the EU Telematics Management Board after consultation of DG Sanco and the governance structure overseeing the implementation of the pharmacovigilance legislation. This functionality has been further elaborated by the PSUR Repository Project Advisory Group, consisting of representatives of the appropriate bodies from the Regulatory Network and Industry.

This version is the one presented on 12 Nov 14 for user acceptance testing by representatives from Industry, EC, NCAs and various Regulatory bodies.

New Change Requests Delivered and Defects Fixed in this Version

ID	Brief Description of the CR or Defect
00035869	Product selection in the UI for Creation of the Delivery File, should be at the level of the "product short name" instead of at the level of the "product presentation".

Known Issues

This section lists the known defects with reference to the formally approved set of requirements. The next releases of the software will address the defects listed here in a prioritised fashion.

Change requests are not listed here.

There are in total 14 open defects listed, of which 0 are classified as "Critical", 0 as "Severe", 6 as "Important" and 8 as "Minor".

ID	Component	Description	Workaround/Comment
00036145	NCA UI	UI Search - drop down lists don't clear when clicking the X	<p>When selecting search criteria in the UI such as Rapp Name if the user makes wrong selection you would expect clicking the "X" would clear the selection. However, this just closes the drop down list. In order to clear selection user has to click on default value. This affects:</p> <ul style="list-style-type: none"> • Rapp Name • Rapp Country • Legal Basis • MA Type
00036288	NCA UI	Product search error in specific navigation scenario	<p>On the search form if trying to search by product the product lookup is not currently finding any products when user types a partial or full product name. The work around is search by active substance or any of the other search criteria.</p>
00036080	eSubmission process	Duplicate submission leads to data being overwritten.	<p>When for 1 same procedure request number the applicants submit zip files with the same name then the content gets overwritten. Documentum can indeed have multiple files with the same name under 1 folder but not multiple folders with the same name.</p>
00036144	NCA UI	System rules regarding the order in which assessment reports should be uploaded have not been implemented	<p>The rules are:</p> <ol style="list-style-type: none"> 1. If a preliminary report for the selected procedure number does not exist then system selects preliminary assessment. This selection cannot be changed by the user. 2. If a preliminary report for the selected procedure number exists then the user can only select preliminary assessment report or "Comments on AR". 3. If an updated assessment report exists then the user can only select "Updated AR" or "Comments on AR".
00036179	DREAM	Problems with the way file extensions are handled by the repository	<p>When a file is uploaded through the UI/API the filename goes in full (i.e. with the extension) into the property 'object_name'. When a file is uploaded through WebTop the filename is stripped from its extension and goes as well into 'object_name'. So when a file uploaded with WebTop is downloaded with the UI then it comes without an extension, which is not right. Action: The upload should strip the filename extension, so that it reproduces what WebTop does.</p>

ID	Component	Description	Workaround/Comment
00036241	NCA UI Delivery File UI	Type-ahead and minimum number of characters to trigger the search	The current type-ahead for products (and other fields) is triggered after at least 4 characters have been entered. This would be a problem if the product to look for has only 3 characters. Ideas for triggers to add to the current trigger: * search for product name is triggered when user hits 'enter'. * search for product name is triggered after x seconds have passed since the last character was entered.
00036244	All	Sentence case in messages	Some of the messages displayed to the users do not use correct sentence case.
00036290	Delivery File UI	UI: Create Delivery File - Reset Button does not reset all fields	If the Create Delivery File form has been filled out either incorrectly or user has created a file and now wants to do another, they can click "Reset" to clear the form. However, not all fields are getting reset. Possibly an IE11 issue as that is where it was reported.
00036294	NCA UI Delivery File UI	Some long drop down lists are getting hidden by other components and/or are not completely visible.	Some long drop down lists are getting hidden by other components and/or are not completely visible.
00036123	Delivery File UI	Legal basis error message is incorrect and is incorrectly formatted.	Currently the error message reads: "Product Has invalid Legal basis" Please use sentence case and correct contents should be: "Submission not required. The submission contains products for which a PSUR is not currently required as per the EURD List."
00036141	Delivery File UI	Procedure Number field ordering	The procedure number field on the create delivery file form does not appear to be ordered correctly. The suggestion is by procedure number then DLP date.
00036206	Delivery File UI	Procedure number field is no longer scrolls just displays as one long list	On the generate Delivery File form the procedure number used to have a scroll bar on it to allow user to scroll down list to the procedure they want. Now it is one long list that goes off the page.
00036236	NCA UI	Product search in search screen does not bring back centralised products	The product search type-ahead/dropdown of the search screen should bring back both CAPS and NAPS in the case that "Subject to EU single assessment" is selected. In the case that 'Subject to EU single assessment ' is not selected, then only NAPS should be searchable.

ID	Component	Description	Workaround/Comment
00036209	NCA UI	Search screen details section shows too much information	The information shown in the Details section of the search screen, when selecting a PSUSA shows too much information. The details shown are indeed for each presentation in the submission but there is some repetition that needs to be filtered out. The product names as displayed should be unique.

Additional Information

None

Annex 1: Severity Classification Scheme as per Standard IEEE 1044

Severity	IEEE 1044 Definition	Possible Examples
1. Critical	Essential operations are unavoidably disrupted, safety is jeopardised, and security is compromised.	<ul style="list-style-type: none"> • Affects all users. • Affects all system usage activities. • Could cause significant loss of revenue. • Will cause interruption of a key process. • Will cause one or more critical business functions to not be available. • Business operations are severely impacted. • Unrecoverable data corruption.
2. Severe	Essential operations are affected but can proceed.	<ul style="list-style-type: none"> • Business is significantly impacted. • A workaround is available, but it is difficult to use. • Creates significant operational risk. • The application is usable but function is severely limited. • Affects most users.

Severity	IEEE 1044 Definition	Possible Examples
		<ul style="list-style-type: none"> • Affects most system usage activities. • Recoverable data corruption.
3. Important	Nonessential operations are disrupted.	<ul style="list-style-type: none"> • A workaround would involve a moderate level of additional user effort. • Creates moderate increase in level of operational risk. • Affects a moderate number of users. • Affects a moderate number of system usage activities. • Can be recovered from at a later stage without impacting Operational Efficiency, Normal revenue flow or the ability to register new deals. • There is some business impact. • The application is usable; less significant functions (not critical to operations) are unavailable or degraded. • These issues may be required to be fixed prior to UAT.
4. Minor	No significant impact on operations.	<ul style="list-style-type: none"> • A workaround would involve little additional user effort. • Carries little operational risk. • Affects a small number of users. • Affects a small number of system usage activities. • Does not impact functionality of the system or cause serious confusion to the user.

Severity	IEEE 1044 Definition	Possible Examples
		<ul style="list-style-type: none"><li data-bbox="929 256 1554 284">• Is not required for delivery prior to Acceptance.<li data-bbox="929 312 1671 339">• Minimal business impact results (more of an annoyance).<li data-bbox="929 368 1554 395">• The problem causes little impact on operations.